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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,284	EHRICHT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 25-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 25-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 July 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 26 July 2004 in which claims 26, 27 and 30 were amended and claims 44-45 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 28 January 2004 under 35 U.S.C. 112, first paragraph, not reiterated below, are withdrawn in view of Applicants comments of pages 8-9 of the response. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Claims 1-19 and 25-45 are under prosecution.

Request for Interview

3. Applicant's request for an interview is acknowledged. If Applicant would like to schedule an interview, it is suggested that Applicant contact the examiner using the contact information found in the conclusion paragraph at the end of this action.

Comments

4. The claims are drawn to a device comprising a chamber body and chamber support placed so as to from a capillary gap between the body and support. The claims contain numerous recitations of adaptations to the device so as to provide functionality to the device e.g. adapted to amplify, characterize, immobilize. However, most of the claims do not define or describe the structural adaptation whereby the functionality is achieved. It is noted that the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

The claims that do not define the structure are given their broadest reasonable interpretation consistent with the claim language and specification. For example, adapted to immobilize is interpreted as encompassing any environment wherein molecules are immobilized or contained (i.e. any indentation, compartment or surface); adapted to characterize is interpreted as encompassing any environment wherein molecule are viewed or tested (i.e. any indentation, compartment or surface); and adapted to amplify is interpreted as encompassing any environment wherein a cell or organism would grow and or multiply (i.e. any indentation, compartment or surface).

Claim Rejections - 35 USC § 112

35 U.S.C. 112: first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 33 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitations "micro-structured temperature sensors include nickel-chromium thick film resistive sensors" and "capillary gap adapted to provide almost simultaneous performance of a chip-based characterization and at least one reprocessing reactions and conditioning reactions" are recited in claims 33 and 40. However, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Response to Arguments

7. Applicant points to page 14, lines 9-13 for support of Claim 33 reciting "temperature sensors include nickel-chromium...". In contrast to Applicant's assertion, the cited passage discusses "heating elements" not sensors as claimed in Claim 33. The specification has been reviewed for a teaching of the claimed sensors, but none has been found. Therefore, neither the cited passage nor the specification as a whole provides support for Claim 33. The rejection is maintained.

Applicant points to page 10, lines 1-8, page 24, lines 4-6 and original Claim 19 for support of Claim 40 "the capillary gap is adapted to provide almost simultaneous performance of chip-based characterization...." The passage on page 10 teaches simultaneous identification of various pathogens and the passage on page 24 teaches "target DNA 50 is amplified according to a typical PCR mechanism and possibly is simultaneously marked." And original Claim 19 recites "the evaluation of the chip-based characterization ensues by a silver precipitation reaction." None of the cited passages teach or support the claimed adaptation of the capillary gap whereby chip-based characterization and reprocessing or conditioning reactions are performed simultaneously. Furthermore, the specification has been reviewed for a description of the claimed adaptation, but none has been found. Therefore, the specification does not provide support for Claim 40. The rejection is maintained.

35 U.S.C. 112: second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 25-30 and 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-30 are indefinite in Claim 25, line 6, for the recitation "the reaction" because the recitation lacks proper antecedent basis in the claim. It is suggested that the claim be amended to provide proper antecedent basis.

Claims 44-45 are indefinite in Claim 44, line 5, for the recitation "the reaction" because the recitation lacks proper antecedent basis in the claim. It is suggested that the claim be amended to provide proper antecedent basis.

Claim 45 is further indefinite for the recitation "work sample" because it is unclear how the term "work" modifies the sample.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5, 8-10, 12-15, 17-19, 25-36 and 38-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 1, Lipshutz et al disclose a device for duplicating and characterizing nucleic acids, the device comprising, a chamber body containing an optically permeable chip (i.e. glass, Column 14, line 35-Column 15, line 29) having a detection area having an optically permeable zone of detection (i.e. transparent window, Column 19, lines 20-29) adapted to

immobilize nucleic acids, peptides or proteins e.g. polymerase enzymes (Column 8, lines 23-42) wherein the chip is placed and sealed on an optically permeable chamber support (i.e. planar glass support, Column 15, lines 9-34) so that a sample chamber having a capillary gap is formed between the chamber support and the detection area (i.e. the reaction chamber is manufactured into the surface of a first planar member which is then covered by a second planar member providing a gap between the first and second planar members, Column 15, lines 9-34) wherein the gap (chamber) is provided with amplification and characterization means i.e. temperature control means for thermocycling and pcr amplification whereby nucleic acids are amplified and characterized via amplification (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Regarding Claim 2, Lipshutz et al disclose the device comprising temperature adjustment means connected to the chamber support and permit rapid temperature control of the gap i.e. provide conditions for PCR amplifications within the chamber (Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Regarding Claim 3, Lipshutz et al disclose the device wherein the temperature adjustment means are situated on the side of the chamber support facing the chamber body (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 4, Lipshutz et al disclose the device wherein the optically permeable zone of detection includes detection spots (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29) and wherein the temperature adjustment means are configured such that the optical transparency of the chip remains unaffected i.e. the "heater insert" is disposed on the side of the chamber thereby not affecting the transparency of the chip Fig 2B #106/112 (Column 24, lines 34-63 and Fig 2B #128).

Regarding Claim 5, Lipshutz et al disclose the device wherein the temperature adjustment means comprises micro-structured heating elements i.e. nickel-chromium film (Column 24, lines 53-59) and micro-structured temperature sensors (Column 25, lines 7-41).

Regarding Claim 8, Lipshutz et al disclose the device wherein the chamber support and body consist of glass ,synthetic material or optically permeable synthetic materials e.g.nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and/or polymethane, ethyl acrylate (Column 15, lines 26-58).

Regarding Claim 9, Lipshutz et al disclose the device wherein the chamber support consists of thermally conducting material i.e. the heating/cooling means are embedded within the support which then conducts the heat to the reaction chamber (Column 27, lines 37-47 and Fig. 8 #806).

Regarding Claim 10, Lipshutz et al disclose the device wherein the chip consists of optically permeable materials e.g. glass (Column 15, lines 25-29).

Regarding Claim 12, Lipshutz et al disclose the device further comprising an inlet and an outlet spatially separate from each other i.e. fluid channel #212 is an inlet for reaction chamber #214 and fluid channel #216 is an outlet for reaction chamber #214 (Fig. 3 and Column 16, lines 12-18).

Regarding Claim 13, Lipshutz et al disclose the device wherein the inlet and outlet are arranged unilaterally and are separated by a gas reservoir nose i.e. gas permeable membrane to allow escape of accumulated gas (Column 17, lines 28-38)

Regarding Claim 14, Lipshutz et al disclose the device wherein the chamber body is sealingly and unreleasbaly connected with the chamber support with an adhesive or welding connection (Column 15, lines 20-29)

Regarding Claim 15, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which nuclei acid probes are immobilized i.e. positionally distinct probes (Column 9, lines 30-35 and Column 9, lines 20-29).

Regarding Claim 17, Lipshutz et al disclose the device wherein the detection area is configured in the form of spots onto which probes in the form or peptides or proteins are immobilized e.g. polymerase enzymes (Column 8, lines 23-42).

Regarding Claim 18, Lipshutz et al disclose the device wherein the capillary gap is adapted to allow characterization by optical detection (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29)

Regarding Claim 19, Lipshutz et al disclose the device is adapted to allow characterization (i.e. transparent window for observation of a "particular analysis", Column 19, lines 20-29). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Lipshutz et al teach the device is adapted for characterization via observation through a transparent window, and because the recitation "by a silver precipitation reaction" does not describe or define additional structural components of the device, the device of Lipshutz et al is encompassed by the instantly claimed device.

Regarding Claim 25, Lipshutz et al disclose a device for duplication and characterizing nucleic acids comprising a chamber support, a chamber body on the support and a capillary gap intermediate the support and body, the gap being adapted to act as a single chamber for both the reaction (e.g. hybridization) and characterization (detection) of nucleic acids (e.g. Fig. 7A; Column 15, lines 9-34; and Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Lipshutz et al teach their device comprises the chamber, support and gap whereby a single chamber is formed for reaction and characterization of nucleic acids. They further teach their device comprises additional reaction chambers. However, a single chamber is formed for hybridization and detection of nucleic acids. Therefore, the device of Lipshutz et al is encompassed by the instant claim.

Regarding Claim 26, Lipshutz et al disclose their device wherein the chamber includes an optically permeable chip (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 27, Lipshutz et al disclose their detection area includes immobilized probes (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 28, Lipshutz et al disclose their immobilized probes include nucleic acids, peptides or proteins (Column 8, lines 23-42; Column 9, lines 30-35; and Column 9, lines 20-29).

Regarding Claim 29, Lipshutz et al disclose the device wherein the detection area is optically permeable (i.e. transparent window, Column 19, lines 20-29).

Regarding Claim 30, Lipshutz et al disclose the device wherein the capillary gap is temperature adjustable and flow controllable. The claim does not require that the device comprise means for temperature adjustment or flow control of the capillary gap. The claim merely requires that the capillary gap be adjustable and controllable. Lipshutz et al teach the temperature and flow within the gap is controlled (Column 27, line 37-Colunn 29, line 67). Therefore, Lipshutz et al teach the device as claimed.

Regarding Claim 31, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 32, Lipshutz et al disclose the device of Claim 1 wherein the temperature adjustment means includes micorstructured sensors (Column 25, lines 7-10).

Regarding Claim 33, Lipshutz et al disclose the device wherein the heating elements include nickel-chromium resistive heaters (Column 24, lines 53-67).

Regarding Claim 34, Lipshutz et al disclose the device of Claim 1 wherein at least one of the chamber support and the chamber body include an optically permeable synthetic materials selected from the group consisting of nylon, Teflon, topaz, polycarbonate, polystyrene, PMMA and polymethane ethyl acrylate (Column 15, line 49-Column 16, line 2).

Regarding Claim 35, Lipshutz et al disclose the device of Claim 1 wherein the chamber includes additional sealing surface adapted to releasable connect to the support (e.g. Column 4, lines 55-58; Column 7, lines 65-67; Column 16, lines 42-45; and Column 23, lines 1-27).

Regarding Claim 36, Lipshutz et al disclose the device of Claim 1 wherein the nucleic acid molecules include DNA or RNA (Column 9, line 30-Column 11, line 57).

Regarding Claim 39, Lipshutz et al disclose the device of Claim 18 wherein the optical detection includes at least one of transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry (Column 12, line 63-Column 13, line 9).

Regarding Claim 40, Lipshutz et al disclose the device of Claim 1 wherein the capillary gap is adapted to provide almost simultaneous performance of characterization and reprocessing or conditioning (i.e. transparent window, Column 19, lines 20-29). The claimed "adapted to provide almost simultaneous performance...." does not define or describe structural components of the device. The transparent window of Lipshutz et al would provide for simultaneous observation and hybridization. However, because the claim recitation does not describe structural limitations of the device, the transparent window of Lipshutz is encompassed by the instantly claimed device.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claims 41-43, Lipshutz et al disclose the device wherein various reactions are performed within a chamber e.g. pcr, transcription (Column 4, lines 1-45). The instantly claimed functions of the device i.e. pcr, reverse transcription, digestive process do not define or describe structural components of the device and therefore do not further limit the claimed device.

Regarding Claim 44, Lipshutz et al disclose a device comprising a chamber support, a chamber body on the support and a capillary gap between the support and body consisting of a single (i.e. multi-dimensional chambers arranged in serial geometry, Column 17, lines 66-

Column 18, line 4). The recitation "for the reaction and characterization of nucleic acids" is a recitation of intended use that does not define or describe structural components of the device.

Regarding Claim 45, Lipshutz et al disclose the device wherein the gap includes means for reacting and means for characterizing (e.g. hybridizing and detecting, Column 15, lines 9-34; and Column 19, lines 1-15 and Column 24, line 34-Column 25, line 41).

Response to Arguments

12. Applicant argues that Lipshutz teaches a plurality of reaction chambers and therefore does not teach the instantly claimed device comprising a single chamber. The argument has been considered but is not found persuasive. First, the open claim language "comprising" recited in the instant claims encompasses any additional elements taught by Lipshutz. The device of Lipshutz comprises a chamber comprising a chamber body and optically permeable support sealed together to form a capillary gap (i.e. well or cavity space forming the reaction chamber between the body and support, Column 15, lines 14-17) whereby the gap forms a single reaction chamber. The single chamber of Lipshutz is illustrated (e.g. Fig. 3) as comprising, on a single support, a region for amplification (#210) and a region for analysis (#218), the regions within the chamber are connected via channels (e.g. #212 and # 216). The device of Lipshutz comprises regions and channels "arranged in serial geometry" but form a single chamber as claimed (Column 17, line 66-Column 18, line 4).

Applicant further argues that Lipshutz does not teach a capillary gap adapted to amplify and characterize nucleic acids as claimed. The argument has been considered but is not found persuasive because as cited above, Lipshutz specifically a single reaction chamber formed by a chamber body and support whereby a gap is formed providing fluid communication between different regions of the device (Column 15, lines 9-31). Applicant appears to be asserting that the capillary gap has a structural relationship with the chamber

body and support other that the relationship described by Lipshutz. However, no such structure is defined by the claims or the taught in the specification.

13. Claims 1, 2, 4, 5, 8-10, 12, 14, 15, 17-19, 25-30, 32, 34-36, 39-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997).

Regarding Claim 1, Woudenberg et al disclose a device comprising a chamber body containing an optically permeable zone of detection (#180, Column 11, lines 11-25 and Fig. 6-9) and an optically permeable support (Column 12, lines 4-10) on which the body is sealingly placed to form a capillary gap (#164) wherein the gap forms a single reaction chamber adapted to amplify and characterize nucleic acids (Column 2, lines 32-46 and Column 3, lines 27-46).

Regarding Claim 2, Woudenberg et al disclose the device further comprising means connected with the chamber for rapid temperature control (Column 3, lines 53-64).

Regarding Claim 4, Woudenberg et al disclose the device wherein the optically permeable zone includes detection spots (#108 or 168) wherein the temperature means are configured such that transparency of the chip is unaffected i.e. a signal is measured at timed intervals during the reaction which could only happen if the transparency remains unaffected (Column 21, lines 29-35).

Regarding Claim 5, Woudenberg et al disclose the device wherein the temperature adjustment means comprise micro-structured heating elements e.g. resistive tracings (Column 21, lines 47-54).

Regarding Claim 8, Woudenberg et al disclose the device wherein the support and body consist of glass, synthetic material or optically permeable synthetic material (Column 11, lines 13-20).

Regarding Claim 9, Woudenberg et al disclose the device wherein the support consists of a thermally conducting material (Column 11, lines 26-29).

Regarding Claim 10, Woudenberg et al disclose the device wherein the chip consists of glass, quartz or silicon (Column 11, lines 13-30).

Regarding Claim 12, Woudenberg et al disclose the device wherein the body includes an inlet (sample inlet #102/162) and outlet (vacuum port #106/216) spatially separate from each other (Fig. 6/9).

Regarding Claim 14, Woudenberg et al disclose the device wherein the body and support are sealingly and unrealeasably connected by adhesive (Column 12, line 58-Column 13, line 18).

Regarding Claim 15, Woudenberg et al disclose the device wherein the detection area is configured in the form of spots (#108 or 168) having nucleic acid probes immobilized i.e. pre-loaded reagents (e.g. nucleic acid probes or primes) are dried thereby immobilized to the detection spot (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 17, Woudenberg et al disclose the device wherein the detection area is configured in the form of spots (#108 or 168) having peptide or proteins i.e. preloaded polymerase (Column 16, lines 13-15).

Regarding Claim 18, Woudenberg et al disclose the device wherein the gap is configured to allow optical or spectroscopy detection (Column 20, lines 10-23).

Regarding Claim 19, Woudenberg et al disclose the device is adapted to allow various forms of detections via optical and non-optical methods (Column 20, lines 10-13). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Because the recitation "by a silver precipitation reaction" does not

describe or define additional structural components of the device, the device of Woudenberg et al is encompassed by the instantly claimed device.

Regarding Claim 25, Woudenberg et al disclose a device comprising a chamber body (#180, Column 11, lines 11-25 and Fig. 6-9), chamber support (#164, Column 12, lines 4-10) and a capillary gap between the body and support wherein the gap forms a single reaction chamber adapted for reaction and characterization nucleic acids (Column 2, lines 32-46 and Column 3, lines 27-46).

Regarding Claim 26, Woudenberg et al disclose the device wherein the body contains an optically permeable chip (#180, Column 11, lines 11-25; Column 12, lines 4-10; and Fig. 6-9).

Regarding Claim 27, Woudenberg et al disclose the device wherein the detection area includes immobilized probes within the gap i.e. pre-loaded reagents (e.g. nucleic acid probes or primers) are dried thereby immobilized to the detection spot (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 28, Woudenberg et al disclose the device wherein the probes include nucleic acids (Column 16, lines 8-20 and Column 19, lines 45-Column 20, line 7).

Regarding Claim 29, Woudenberg et al disclose the device wherein the detection area is optically permeable (e.g. Column 12, lines 4-10).

Regarding Claim 30, Woudenberg et al disclose the device wherein the gap is temperature adjustable and flow-controllable (i.e. sample distribution network) (Column 13, lines 19-27 and 54-64).

Regarding Claim 32, Woudenberg et al disclose the device wherein the temperature adjustment includes microstructured temperature sensors i.e. temperature feedback (Column 26, lines 10-13).

Regarding Claim 34, Woudenberg et al disclose the device wherein the optically permeable material is polycarbonate or polystyrene (Column 10, lines 662-65 and Column 11, lines 13-20).

Regarding Claim 35, Woudenberg et al disclose the device further comprising an additional sealing surface i.e. inlet seal (Column 14, lines 56-63).

Regarding Claim 36, Woudenberg et al disclose the device wherein the nucleic acids are DNA or RNA (Column 15, lines 25-38).

Regarding Claim 39, Woudenberg et al disclose the device wherein the optical detection includes at least one of transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry (Column 20, lines 13-23).

Regarding Claim 40-43, Woudenberg et al disclose the device wherein characterization (i.e. detection) is performed during reaction (i.e. at selected time points) and therefore, "almost" simultaneously as claimed (Column 21, lines 29-35). Woudenberg et al further teach various reactions are performed within the chamber e.g. PCR, ligation, primer extension and etc (Column 3, lines 28-38). The instantly claimed "adapted to perform" does not define or describe structural elements of the device. Because Woudenberg et al specifically teach the claimed structural elements, because Woudenberg et al teach various reactions performed within the device, and because the instant claims do not define further structural components of the device, Woudenberg et al teach the device as claimed.

Regarding Claim 44, Woudenberg et al disclose a device comprising a chamber body (#180, Column 11, lines 11-25 and Fig. 6-9), chamber support (#164, Column 12, lines 4-10) and a capillary gap between the body and support wherein the gap forms a single reaction chamber adapted for reaction and characterization nucleic acids (Column 2, lines 32-46 and Column 3, lines 27-46).

Regarding Claim 45, Woudenberg et al teach the device comprising means for reacting (e.g. reagents) and means for characterizing (e.g. optically transparent window) (Column 5, lines 17-40)

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) or Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) in view of McBride et al (U.S. Patent No. (6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 6 and 7, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not teach the a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the

electrodes of Lipshutz et al or Woudenberg et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

Response to Arguments

16. Applicant argues that McBride does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) or Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) in view of Atwood et al (U.S. Patent No. 5,475,610, filed 20 April 1992).

Regarding Claim 11, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not teach the reaction chamber comprises a conical recess. However, it was well known in the art at the time the claimed invention was made that the preferred surface for PCR reactions comprise conical recesses as taught by Atwood et al (Column 12, lines 28-47). Atwood et al further teach that conical recesses provide very tight temperature control for all samples and within each sample throughout the PCR cycles (Column 12, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the conical recess of Atwood et al to the PCR reaction chamber of Lipshutz et al or Woudenberg et al thereby providing means for very tight temperature control for the expected benefit of controlling temperature of each sample throughout the PCR cycles as taught by Atwood et al (Column 12, lines 40-47).

Response to Arguments

18. Applicant argues that Atwood does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

19. Claim 16, 17 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999) or Woudenberg et al (U.S. Patent No. 6,126,899, filed 2 April 1997) in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claims 16 and 37, the devices of Lipshutz et al and Woudenberg et al are discussed above. They do not specifically teach the probes are immobilized through spacers. However, Fodor et al do teach their probes are immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Lipshutz et al or Woudenberg et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Regarding Claim 17, Lipshutz et al teach the device wherein proteins are immobilized (Column 8, lines 39-42) but they do not teach the detection area comprises probes in the form of spots. However, detection areas (arrays) comprising spots of protein probes were well known in the art at the time the claimed invention was made as taught by Fodor et al who

teach the peptide array provide a tool for high-density peptide-specific antibody recognition (Column 8, line 61-Column 9, line 30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the peptide probes of Fodor et al to the detection area of Lipshutz et al to thereby provide for high-density antibody screening for the expected benefits of determining relative binding affinity between a plurality of peptides simultaneously as taught by Fodor et al (Column 2, lines 44-49).

Regarding Claim 38, Lipshutz et al teach the device wherein the proteins included receptor molecules e.g. antibodies (Column 8, lines 36-42).

Response to Arguments

20. Applicant argues that Fodor does not teach the elements missing from and discussed above regarding Lipshutz and therefore the above rejection is improper. The argument has been considered but is not found persuasive for the reasons stated above regarding Lipshutz.

Conclusion

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Art Unit: 1634
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